MAY - 1 2003

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Laura D. Williams, RAC Sr. Associate, Regulatory Affairs Telephone: (574) 372-4523 Fax: (574) 372-4605
Date:	March 7, 2003
Trade Name:	*MAYO*®* Conservative Hip Prosthesis
Common Name:	Total hip prosthesis
Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR § 888.3358
Predicate Devices:	*MAYO* Conservative Hip Prosthesis, manufactured by Zimmer, K943230, cleared January 14, 1997 *VerSys*® Fiber Metal Taper Hip Prosthesis, manufactured by Zimmer, K964769, cleared February 13, 1997 Harris/Galante Hip System with *Calcicoat*® Ceramic Coating, manufactured by Zimmer, K980711, cleared November 12. 1998
Device Description:	Like the predicate *MAYO* Hip, the *MAYO* 12/14 Hip Prosthesis is a modular femoral stem intended to replace the hip joint in total hip arthroplasty. It is used with a variety of modular femoral heads. The stem is collarless, wedge-shaped, and is intended for use without bone cement. Fixation is achieved by biological ingrowth into the fiber metal pads and by mechanical press fit into the proximal femoral shaft.
Intended Use:	The *MAYO* 12/14 Conservative Hip Prosthesis is indicated for cementless use in skeletally mature individuals undergoing primary surgery for total hip

*Trademark of Mayo Foundation

	replacement. Diagnostic indications include severe hip pain and disabilities due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, slipped capital femoral epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.
Comparison to Predicate Device:	The *MAYO* 12/14 Hip is packaged, manufactured and sterilized using the same materials and processes as the predicates. The *MAYO* 12/14 Hip will be available with a 12/14 Morse-type taper neck, and with or without HA/TCP coating.
Performance Data:	Non-clinical performance testing demonstrated that the device is equivalent to the predicate.

*Trademark of Mayo Foundation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2003

Ms. Laura D. Williams, RAC
Sr. Associate, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Re: K030733
Trade/Device Name: MAYO® Conservative Hip Prosthesis
Regulation Number: 888.3358
Regulation Name: Hip joint/metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: March 7, 2003
Received: March 10, 2003

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

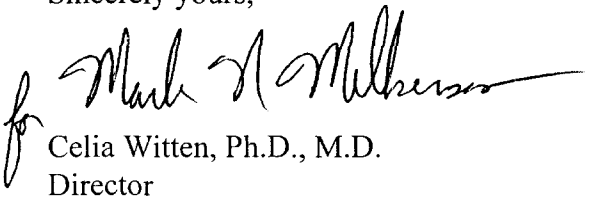
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K030733

Device Name:

MAYO® Conservative Hip Prosthesis

Indications for Use:

The *MAYO* Conservative Hip Prosthesis is indicated for cementless use in skeletally mature individuals undergoing primary surgery for total hip replacement. Diagnostic indications include severe hip pain and disabilities due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, slipped capital femoral epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhozn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030733

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)